K103227

APR 11 2012

510(k) Summary (as required by section 807.92(c)

Traditional 510(k) Premarket Notification
Oratect® Oral Fluid Drug Screen Devices

Date Prepared: 10/29/10
Date Updated: **02/01/12**

510 (K) Owner

Raphael Wong
Branan Medical Corp.
140 Technology Drive
Irvine, CA 92618

Phone: (949)-598-7166
Fax: (949)-598-7167
Email: raphael@brananmedical.com

Correspondent

Huiying Wang, Ph.D
Director of Research & Development
Branan Medical Corporation

Phone (949)-598-7166, ext. 135
Fax: (949)-727-2131
Email: hwang@brananmedical.com

Device Name

Trade or Proprietary Name(s):	Oratect® Oral Fluid Drug Screen Device	OratectCheck™ Oral Fluid Controls
Common or Usual Name:	Immunochromatographic test for the qualitative detection of drugs in oral fluid (human saliva)	Drug Specific Control Materials to monitor and validate the qualitative performance of the device.
	d-Amphetamines Test Systems (AM)	Positive Control Negative Control
	Delta-9-Tetrahydrocannabinol (TH)	
	Cocaine Test Systems (CO)	
	d-Methamphetamines Test Systems (ME)	
	Opiates Test Systems (OP)	
	Phencyclidine Test Systems (PC)	
Product Classification	Class II	Class I
Classification Name:	Lateral Flow Immunoassay, Amphetamine, Cocaine, Methamphetamine, Cannabinoids, Opiates and Phencyclidine	Drug Mixture Control Materials
	See Details Below	

Descriptions	Title and CFR Part	Review Panel	Regulation Number	Product Code
d-Amphetamines Test Systems (AM)	Title 21 Part 862 Clinical Chemistry and Clinical Toxicology	Clinical Toxicology Test Systems	**862.3100**	DKZ
Delta-9-Tetrahydrocannabinol (TH)			**862.3870**	LDJ
Cocaine Test Systems (CO)			**863.3250**	DIO
d-Methamphetamines Test Systems (ME)			**862.3610**	DJC
Opiates Test Systems (OP)			**862.3650**	DJG
Phencyclidine Test Systems (PC)			**862.3100**	LCM
OratectCheck™ Saliva/Oral Fluid Controls (Positive and Negative)	Title 21 Part 862 Clinical Toxicology control Material	Toxicology	**862.3280**	DIF

Substantial Equivalency

The Oratect® Oral Fluid Drug Screen Device Test is substantially equivalent to the following Intercept® Micro-plate EIAs manufactured by OraSure Technologies Inc. (formerly known as STC Technologies, Inc) for its general intended use.

Device Description	Predicate Device Name	Predicate Device 510(k) #
Amphetamine	Amphetamine-Specific Intercept® Micro-plate EIA	K992918
Cocaine	Cocaine Metabolites Intercept® Micro-plate EIA	K001197
Methamphetamine	Methamphetamine Intercept® Micro-plate EIA	K001197
Cannabinoids	Cannabinoids Intercept® Micro-plate EIA	K002375
Opiates	Opiates Intercept® Micro-plate EIA	K981341
Phencyclidine	PCP Intercept® Micro-plate EIA	K000399

Product Comparison to Predicate Device

Device Characteristics	Subject Device (BMC Oratect® Oral Fluid Drug Screen Device)	Predicate Devices (OraSure Intercept® Micro-plate EIAs)	Substantially Equivalent
Specimen Type	Oral Fluid (human saliva)	Oral Fluid (human saliva)	Yes
Drug Analytes	d-Amphetamine, Cocaine, d-Methamphetamine, Cannabinoids, Opiates, and PCP	d-Amphetamine, Cocaine, d-Methamphetamine, Cannabinoids, Opiates, and PCP	Yes
Intended Use	Preliminary Drug screening test for the qualitative detection of drug analytes in oral fluid (human saliva). For *In Vitro* Diagnostic Use	Preliminary Drug screening test for the qualitative detection of drug analytes in oral fluid (human saliva) For *In Vitro* Diagnostic Use	Yes
Test Principle/ Methodology	Specific non radioisotope immunoassay. The assay of small drugs of abuse molecules are based on the competitive immunoassay methodology, the presence of analyte will produce a negative signal. Competitive lateral flow immunochromato-graphic assay	Specific non radioisotope immunoassay. The assay of small drugs of abuse molecules are based on the competitive immunoassay methodology, the presence of analyte will produce a negative signal. Competitive Enzyme-labeled immunoassay	Yes
Assay Cut-off Values	Preset cut-off values used to differentiate a positive sample from a negative sample. Oratect® Oral Fluid Drug Screen Devices use the cut-off values established by SAMHSA except for Cannabinoids. The THC test sensitivity limitation is 40 ng/mL.	Preset cut-off values used to differentiate a positive sample from a negative sample. OraSure Intercept® Micro-plate EIA system sets up a cut-off value level based on the LOD = AO-3 SD	Yes
Assay Conditions	Tests performed at room temperature and visually interpreted. Oratect® Oral Fluid Drug Screen Devices are a point of care (POC) test which can be performed in less than fifteen (15) minutes test time.	Tests performed at room temperature and utilizing instrument interpretation. OraSure Intercept® Micro-plate EIA system test require laboratory instrumentation, multiple steps and up to ninety (90) minutes test time.	Yes
Reference Test Method	For a quantitative result or for a confirmation of a presumptive positive result obtained by the Oratect® Oral Fluid Drug Screen Device, a more specific alternative confirmatory method such as LC/MS/MS must be used.	A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.	Yes

Device Characteristics	Subject Device (BMC Oratect® Oral Fluid Drug Screen Device)	Predicate Devices (OraSure Intercept® Micro-plate EIAs)	Substantially Equivalent
Accuracy	Accuracy results against reference method >90%	Accuracy results against reference method >89%	Yes
Precision	Oratect® Oral Fluid Drug Screen Devices were evaluated at three (3) Point of Care (POC) sites and the overall precision was above 90%	OraSure Intercept® Micro-plate EIA system Tests are an instrument dependent method and the assay imprecision was less than 10%.	Yes
Cross reactants and Interference compounds	Oratect® Oral Fluid Drug Screen Devices use very specific antibodies for their respective test. Only a limited number of structure related chemicals cross react with the tests. A list of cross reactants and interference compounds are presented in the product package insert. The package insert also includes a list of food ingredients.	OraSure Intercept® Micro-plate EIA system Devices use very specific antibodies for their respective test. Only a limited number of structure related chemicals cross react with the tests. A list of cross reactants and interference compounds are presented in the product package insert.	Yes
Test Result Interpretation	Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.	Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.	Yes
Testing Site	Point-of Care	Laboratory	No

Test Summary:

Performance data

The performance of the BMC Oratect® Oral Fluid Drug Screen Devices was determined in analytical performance validation studies, precision site studies and in method comparison studies comparing the BMC Oratect® Oral Fluid Drug Screen Devices against LC/MS or GC/MS reference test method.

The performance characteristics of the BMC Oratect® Oral Fluid Drug Screen Devices were based on evaluations by the following analytical and clinical performance tests:

1.0 Test method comparison (pipette adding vs. oral swab)
2.0 Optimal Read Time Window
3.0 Specificity/Cross Reactivity
4.0 Interferences and Effect of Food Interference
5.0 Product Stability
6.0 Precision Site Study
7.0 Comparison Study

Conclusion:

The above substantial equivalence comparison demonstrates that the BMC Oratect® Oral Fluid Drug Screen Devices are as safe and effective and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Branan Medical Corporation
Attn: Huiying Wang, Ph.D.
Director of Research & Development
140 Technology Drive
Suite 400
Irvine, CA 92618

APR 11 2012

Re: k103227
Trade Name: Oratect Oral Fluid Drug Screen Devices and OratectCheck Oral Fluid Controls
Regulation Number: 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Codes: DKZ, DJC, DIO. DJG, LCM, LDJ, DIF
Dated: April 09, 2012
Received: April 10, 2012

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4.0 **Indications for Use Statement**

510(k) Number (if known): K103227

Device Name(s): 1. Oratect® Oral Fluid Drug Screen Devices (see table below)

2. OratectCheck™ Oral Fluid Controls

The Oratect® Oral fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of d-Methamphetamine (ME), Delta-9-Tetrahydrocannabinol (TH), Cocaine (CO), d-Amphetamine (AM), Morphine (OP) and Phencyclidine (PC) in human oral fluid. The Oratect® tests detect these drugs at the cutoff concentration listed below.

Test	Cutoff
Oratect® Oral Fluid Drug Screen Device d-Amphetamine	50 ng/mL
Oratect® Oral Fluid Drug Screen Device d-Methamphetamine	50 ng/mL
Oratect® Oral Fluid Drug Screen Device Delta-9-Tetrahydrocannabinol	40 ng/mL
Oratect® Oral Fluid Drug Screen Device Cocaine	20 ng/mL
Oratect® Oral Fluid Drug Screen Device Morphine	40 ng/mL
Oratect® Oral Fluid Drug Screen Device Phencyclidine	10 ng/mL

These products are for *in vitro diagnostic use* and intended for prescription point of care use.

The Oratect® Oral Fluid Drug Screen Device provides only preliminary drug test results. A more specific alternative method must be used in order to obtain a confirmed analytical result. Liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) is the preferred confirmatory method. Samples for confirmatory testing should be collected with the Oratect® Oral Fluid Collection Tube (50 mL polypropylene tube) provided. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

OratectCheck™ Oral Fluid Controls (Negative and Positive controls of the analytes) are available but not supplied with the Oratect® Oral Fluid Drug Screen Devices. The OratectCheck™ Oral Fluid Controls are used as quality control materials with Oratect® Oral Fluid Drug Screen Devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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